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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,664	06/26/2003	Takatomo Hisamatsu	018961-063	3993

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EXAMINER
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RYCKMAN, MELISSA K

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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02/19/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/603,664	HISAMATSU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MELISSA RYCKMAN	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 September 2007 and 26 November 2007.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-26 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/07 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 3, 5, 6, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al. (US 6,036,670) in view of Berg et al. (US 5,911,715).

Wijeratne teaches a catheter comprising the following: a proximal shaft (32); a distal shaft (22) connected to a front portion of said proximal shaft; a hub (34) provided to the rear side of said proximal shaft; a balloon (21) provided at a front portion of said distal shaft; an inner tube shaft (23) coaxially extends through said distal shaft and said balloon and connected at a distal end of said balloon (fig. 1); a balloon lumen for communicating said hub to the inside of said balloon; and a guide wire lumen (23) for

allowing a guide wire to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (25) positioned on the distal side from a front end of said balloon and a proximal side aperture (26) positioned on the rear side from a rear end of said balloon;

Wijeratne fails to teach the following:

- wherein at least a front portion, positioned on the rear side from said balloon, of said distal shaft is configured as a grooved portion having a groove, said grooved portion has a distal end locate near a connection portion between said balloon and said distal shaft and extends toward a proximal side of said distal shaft
- wherein said groove is formed into spiral shape or annular shape.
- wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter.
- wherein the depth of said groove is in a range of 30 to 90% of the wall thickness of said distal shaft.
- wherein the depth of said groove is changed in the direction toward the distal end of said catheter.
- wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in said second region is larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region.
- wherein said grooved portion is provided at a portion adjacent to said balloon.

- wherein said groove is formed in an outer surface of said distal shaft.
- said groove possessing a depth which changes relative to a longitudinal extent of the distal shaft so as to be relatively larger on a distal side of said grooved portion and relatively smaller on a proximal side of said grooved portion.

Berg teaches a guide catheter capable of carrying a balloon wherein, at least a front portion, of said distal shaft (56) is configured as a grooved portion having a groove (61), said grooved portion has a distal end located near a connection portion (it is noted that the term near is broad and may encompass a location anywhere along the device, and further a connection portion may simply be the transition between balloon and the distal shaft portion) between said balloon and said distal shaft and extends toward a proximal side of said distal shaft, wherein said groove is formed into spiral shape or annular shape (fig. 10), wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein the depth of said groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in said second region is larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region (fig. 1 lc) and wherein said groove is formed in an outer surface of said distal shaft (fig. 9) in order to provide a device having increased flexibility for better maneuverability. Berg teaches said groove possessing a depth

which changes relative to a longitudinal extent of the distal shaft (Fig. 11) so as to be relatively larger on a distal side of said grooved portion and relatively smaller on a proximal side of said grooved portion.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Wijeratne with the grooved portion as taught by Berg in order to provide a device having increased flexibility for better maneuverability.

Claims 1,2, 7, 8, 10-14, 16-20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith (US 5217482)in view of Berg (US 5911715).

Keith teaches a catheter comprising the following:

- a proximal shaft (22); a distal shaft (66) connected to a front portion of said proximal shaft (22); a hub (42) provided to the rear side of said proximal shaft; a balloon (26) provided at a front portion of said distal shaft (fig. 1); an inner tube shaft (84) coaxially extends through said distal shaft and said balloon and connected at a distal end of said balloon (fig. 1) balloon lumen (106) for communicating said hub (Column 5, proximate lines 55-58) to the inside of said balloon; and a guide wire lumen (52) for allowing a guide wire (50) to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (94) positioned on the distal side from a front end of said balloon (26) and a proximal side aperture (92) positioned on the rear side from a rear end of said balloon (26);

- a proximal shaft (22) having a high rigidity (Column 6, proximate liens 60-65), a distal shaft (66) provided on a front portion of said proximal shaft so as to be in fluid communication with said proximal shaft (Fig. 2) and having a rigidity lower than that of said proximal shaft (Column 8, proximate lines 36-40); a hub (42) connected to the vicinity of a rear end of said proximal shaft (22) and configured to allow a pressure applying apparatus to be connected to said hub (Column 5, proximate lines 55-58); a balloon (56) provided on a front side of said distal shaft so as to be in fluid communication with said distal shaft and a guide wire lumen (52) for allowing a guide wire to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (94) positioned on the front side from a front end of said balloon and a proximal side aperture, positioned on the rear side (92) from a rear end of said balloon;
- wherein said distal shaft is made from a polymer material having a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cmz or more (Column 7, proximate lines 34-36). Keith teaches wherein the distal shaft is formed of a high-density polyethylene, which inherently has a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cm<sup>2</sup>.
- wherein said distal shaft has a distal portion (34) and a proximal portion (110), and the rigidity of said proximal portion (110) of said distal shaft is lower than that of said proximal shaft (22) and is higher than that of said distal portion (34) of said distal shaft (Column 9, proximate lines 1-10).

Keith fails to teach the following:

- wherein at least a front portion, positioned on the rear side from said balloon, of said distal shaft is configured as a grooved portion having a groove said grooved portion has a distal end locate near a connection portion between said balloon and said distal shaft and extends toward a proximal side of said distal shaft
- A catheter according to claim 12, wherein said groove is formed into spiral shape or annular shape.
- A catheter according to claim 12, wherein said grooved portion is provided at a portion adjacent to said balloon.
- wherein said groove is formed in an outer surface of said distal shaft.
- wherein said grooved portion is positioned on the rear side from said balloon
- wherein the pitch of said spiral or annular groove is changes over the length of the grooved portion of the distal catheter

Berg teaches a guide catheter capable of carrying a balloon wherein, at least a front portion, of said distal shaft (56) is configured as a grooved portion having a groove (61), said grooved portion has a distal end locate near a connection portion (it is noted that the term near is broad and may encompass a location anywhere along the device, and further a connection portion may simply be the transition between balloon and the distal shaft portion) between said balloon and said distal shaft and extends toward a proximal side of said distal shaft, wherein said groove is formed into spiral shape or annular shape (fig. 10), wherein the pitch of said spiral or annular groove is changed in

the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein the depth of said groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in said second region is larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region (fig. 1 lc) and wherein said groove is formed in an outer surface of said distal shaft (fig. 9) in order to provide a device having increased flexibility for better maneuverability. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Keith with the grooved portion as taught by Berg in order to provide a device having increased flexibility for better maneuverability.

Regarding the limitation wherein the pitch of said spiral or annular groove is changes over the length of the grooved portion of the distal catheter, Berg teaches a catheter wherein the grooved portion may have varying width and depths in order to provide variation in flexibility from groove to groove. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Keith with varying pitch of the spiral groove in order to provide variation in flexibility along the grooved portion.

Claims 4, 9, 15, 21, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Keith and Berg as applied to claims 1 and 12 above, and further as a matter of design choice.

The combination of Keith and Berg teaches all of the limitations of preceding dependent claims 1 and 12 as previously disclosed, but fails to describe the following:

- wherein the depth of said groove is in a range of 30 to 90% of the wall thickness of said distal shaft.
- wherein the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more.

Regarding the limitations wherein the groove is in a range of 30 to 90% of the wall thickness of said distal shaft and the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more, the combination of Keith and Berg teaches a device wherein the grooves are in place in order to provide a smooth transition from the proximal rigid portion to the more flexible distal portion (Berg), but does not teach the exact depth of the grooves in relation the thickness of the shaft. It appears that the combination of Keith and Berg performs the task of providing a smooth transition from the proximal rigid portion to the more flexible distal portion equally well as that disclosed in the application. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose make the depth of the groove in a range of 30 to 90% of the wall thickness of the distal shaft and the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more since it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### ***Response to Arguments***

Applicant's arguments filed 10/30/07 have been fully considered but they are not persuasive. The applicant generally argues the following:

- Berg discloses a guide catheter 54, and does not disclose a balloon

The examiner respectfully disagrees with the applicant, in addition to the motivation to combine as stated above, another 103 (a) combination of Keith and Berg would be a "simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement." KSR, 550 U.S. \_\_, 82 USPQ2d 1385 (2007). The shaft of Keith can be substituted by the shaft of Berg, thus fulfilling the structure as defined in the claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

/ (Jackie) Tan-Uyen T. Ho/  
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